



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-1720]

Labeling of Foods Comprised of or Containing Cultured Seafood Cells; Request for Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for information.

SUMMARY: The Food and Drug Administration (FDA or we) is requesting information pertaining to the labeling of foods comprised of or containing cultured seafood cells. Foods comprised of or containing cultured seafood cells are being developed and may soon enter the marketplace. Therefore, we intend to use information and data resulting from this notice to determine what type(s) of action, if any, we should take to ensure that these foods are labeled properly.

DATES: Submit either electronic or written comments on the notice by [INSERT DATE 150 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments and information as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before [INSERT DATE 150 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 150 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Comments received by mail/hand

delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2020-N-1720 for "Labeling of Foods Comprised of or Containing Cultured Seafood Cells; Request for Information." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469,

September 18, 2015, or access the information at:

<https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Andrea Krause, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2371.

SUPPLEMENTARY INFORMATION:

I. Background

A. FDA Jurisdiction Over Cultured Animal Cells

Efforts are underway to develop various food products comprised of or containing cultured animal cells, including cells from livestock, poultry, and seafood¹ species, using a process often referred to as animal cell culture technology. Animal cell culture technology involves the controlled growth of animal cells, their subsequent differentiation into various cell types, and their harvesting and processing into food. Once produced, the harvested cells could potentially be processed into or combined with other foods and marketed in the same, or similar, manner as conventionally produced meat, poultry, and seafood. In this document we refer to these foods as "foods comprised of or containing cultured animal cells." Many companies, both

¹ The use of the term "seafood" refers to all fish (freshwater and saltwater) and other seafood species (e.g., molluscs, crustaceans) under FDA jurisdiction.

domestic and foreign, are developing products using this technology. Given these technological advances, it is appropriate to consider what actions, if any, may be needed to ensure the safe production and accurate labeling of these products.

FDA will be involved in the regulation of foods generated by animal cell culture technology consistent with our current legal authorities. We are responsible for implementing and enforcing the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 301 *et seq.*), the Public Health Service Act (42 U.S.C. 201 *et seq.*), and the Fair Packaging and Labeling Act (15 U.S.C. 1451 *et seq.*). In carrying out our responsibilities under these laws, we maintain responsibility for ensuring that food is safe and not misbranded.

B. Relevant Misbranding Provisions under the FD&C Act

This document primarily pertains to representations about the identity of foods comprised of or containing cultured seafood cells. Such representations include the name of the food and descriptions about its nature, source, or characteristics. There are several provisions in the FD&C Act under which food may be misbranded with respect to representations about identity. In general, the representations made or suggested must not cause the labeling to be misleading, either affirmatively or by omission of material facts (21 U.S.C. 343(a)(1) and 321(n)). The FD&C Act prohibits offering a food for sale under the name of another food (21 U.S.C. 343(b)). It requires the labels of non-standardized foods to bear the common or usual name of the food if such a name exists (21 U.S.C. 343(i)(1)). Common or usual names are generally established by common usage, though in some cases may be established by regulation pursuant to the principles in 21 CFR 102.5(a)-(c) (see 21 CFR 102.5(d)). In the absence of a common or usual name or other name established by federal law or regulation, food sold in packaged form is required to be labeled with an accurate description of the food or a fanciful name commonly used by the public

(§ 101.3(b)(3) (21 CFR 101.3(b)(3))). Such description or name must not be false or misleading (21 U.S.C. 343(a)(1)) and is referred to as the statement of identity (§ 101.3(b)). Finally, the FD&C Act provides that words or statements required to appear on the label or labeling be in such terms as to render them likely to be understood by the ordinary individual under customary conditions of purchase and use (21 U.S.C. 343(f)).

C. FDA-USDA Agreement Regarding Oversight of Human Food Produced Using Animal Cell Technology Derived from Cell Lines of USDA-Amenable Species

In November 2018, FDA and the U.S. Department of Agriculture (USDA) formally announced that they will jointly oversee the production of cultured cell food products derived from livestock and poultry (Ref. 1). On March 7, 2019, FDA and USDA signed an agreement that described each entity's intended roles with respect to the oversight of human food produced using animal cell culture technology, derived from cell lines of those species² covered under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*) (Ref. 2). In summary, FDA will oversee the collection, growth and differentiation of livestock and poultry cells until cell harvest. A transition from FDA to USDA's Food Safety and Inspection Service oversight will occur during the cell harvest stage. USDA then will oversee the processing, packaging, and labeling of the resulting food products derived from the cultured cells of livestock and poultry. FDA will continue to regulate foods comprised of or containing cultured animal cells from other species under FDA's jurisdiction, such as seafood species other than Siluriformes fish.

² Products made from cattle, sheep, swine, goats, and Siluriformes fish are subject to the FMIA. Products made from domesticated chickens, turkeys, ducks, geese, guineas, ratites, and squab are subject to the PPIA.

In the FDA-USDA agreement, FDA and USDA have agreed to develop joint principles for product labeling and claims to ensure that products are labeled consistently and transparently.

D. Public Meetings on Animal Cell Culture Technology

Participation in public meetings is an important opportunity to share our current thinking on the science surrounding new technologies, how our regulatory framework may apply to new technology, and most importantly, to hear from the public. On July 12, 2018, we held a public meeting, "Foods Produced Using Animal Cell Culture Technology," to give the public an opportunity to provide comments related to the production of foods using animal cell culture technology. In this meeting, we discussed our expected involvement in the oversight of products of cell culture technology and solicited feedback from stakeholders. Building on this effort, on October 23 to 24, 2018, USDA and FDA hosted a joint public meeting entitled, "Joint Public Meeting on the Use of Cell Culture Technology to Develop Products Derived From Livestock and Poultry." This meeting presented the opportunity for FDA and USDA to hear from stakeholders about various issues, including the labeling of food products comprised of or containing cultured livestock and poultry cells.

II. Issues for Consideration and Request for Information

We invite comment in response to the questions below. Our use of the term "cultured seafood cells" in these questions is intended to distinguish between the foods, which are the subject of this document, and conventionally produced seafood. It is not intended to establish or suggest nomenclature for labeling purposes. The names and descriptions in food labeling should be based on consumer understanding and usage as described in section I.B.

We invite comment, particularly data and other evidence, about: (1) names or statements of identity for foods comprised of or containing cultured seafood cells; (2) consumer

understanding of terms that have been suggested for the names or statements of identity of foods comprised of or containing cultured seafood cells; and (3) how to assess material differences between the foods that are the subject of this document and conventionally produced foods. In responding to these questions, please identify the question by its associated letter and number (such as "2(a)") so that we can associate your response with a specific question.

1. Should the name or statement of identity of foods comprised of or containing cultured seafood cells inform consumers about how the animal cells were produced? Please explain your reasoning.
2. What terms should be in the name or statement of identity of a food comprised of or containing cultured seafood cells to convey the nature or source of the food to consumers? (For example, possible terms could be "cell cultured" or "cell based" or "cell cultivated.") Please explain your reasoning and provide any studies or data about consumer understanding of such terms.
 - a. How do these terms inform consumers of the nature or source of the food?
 - b. If foods comprised of or containing cultured seafood cells were to be labeled with the term "culture" or "cultured" in their names or statements of identity (e.g., "cell culture[d]"), would labeling differentiation be necessary to distinguish these products from other types of foods where the term "culture" or "cultured" is used (such as "aquaculture")? Please explain your reasoning and provide any studies or data about consumer understanding of such terms.
3. The names of many conventionally produced seafood products have been established by common usage or by statute or regulation. Names are also recommended for seafood

species in *The Seafood List*³. In FDA's view, foods comprised of or containing cultured seafood cells are not yet in the marketplace and, therefore, do not have common or usual names established by common usage.

- a. If you disagree with FDA's view, what are these names and what evidence demonstrates that the names are commonly used and understood by the American public for foods derived from cultured animal cells?
 - b. Should names for conventionally produced seafood products established by common usage, statute, or regulation be included in the names or statements of identity of food derived from cultured seafood cells? Please explain your reasoning.
 - c. If so, is additional qualifying language necessary? What qualifying terms or phrases would be appropriate? Please explain your reasoning.
 - d. Do these names, with or without qualifying language, clearly distinguish foods derived from seafood cell culture from conventionally produced seafood? Please explain your reasoning.
 - e. Should FDA update *The Seafood List* to include foods comprised of or containing cultured seafood cells? Please explain your reasoning.
4. Should terms that specify a certain type of seafood (such as "fillet" or "steak") be included in or accompany the name or statement of identity of foods comprised of or containing cultured animal cells?
 - a. Under what circumstances should these terms be used? What information would they convey to consumers? For example, would such terms convey the physical form or

³ *The Seafood List* provides guidance to industry about specificity in the naming of seafood sold in interstate commerce and to assist manufacturers in labeling seafood products.

- appearance of the food? Please explain your reasoning. Additionally, please provide any studies or data about consumer understanding of such terms when used to describe foods comprised of or containing cultured seafood cells.
- b. Would these terms be misleading to consumers? Please explain your reasoning and provide any supporting studies or data.
5. When comparing conventionally produced seafood to foods comprised of or containing cultured seafood cells, what attributes (such as nutrition, taste, texture, or aroma) vary between the foods and should FDA consider to be material to consumers' purchasing and consumption decisions? Please explain your reasoning.
- a. Are there other characteristics beyond nutritional attributes or organoleptic properties that may be material differences? These could relate either to cellular constituents or characteristics influenced by the cell culture production process. Please be specific in your response and explain your reasoning.

III. References

The following references are on display at the Dockets Management Staff (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov>. FDA has verified the website addresses, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

1. FDA, Statement from USDA Secretary Perdue and FDA Commissioner Gottlieb on the Regulation of Cell Cultured Food Products from Cell Lines of Livestock and Poultry, Nov. 16, 2018, available at <https://www.fda.gov/news-events/press-announcements/statement-usda-secretary-perdue-and-fda-commissioner-gottlieb-regulation-cell-cultured-food-products>.

2. Formal Agreement Between FDA and USDA Regarding Oversight of Human Food Produced Using Animal Cell Technology Derived from Cell Lines of USDA-amenable Species, March 7, 2019, available at <https://www.fda.gov/food/domestic-interagency-agreements-food/formal-agreement-between-fda-and-usda-regarding-oversight-human-food-produced-using-animal-cell>.

Dated: October 1, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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